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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,116	01/24/2002	Todd K. Whitehurst	AB-165U	1864

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ADVANCED BIONICS CORPORATION
25129 RYE CANYON ROAD
VALENCIA, CA 91355

EXAMINER	
SCHAETZLE, KENNEDY	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,116	WHITEHURST ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *12-14 and 23-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 15-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-11 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al. (Pat. No. 6,185,452).

Regarding claim 1, Schulman discloses providing at least one leadless stimulator (100) having at least two electrodes (112a and 112b), implanting the at least one stimulator adjacent to at least one nerve (see col. 2, lines 16-23), at least in part responsible for sensations in a region experiencing pain (note col. 3, lines 30-34); providing operating power to the at least one stimulator (see text abridging cols. 3 and 4), using at least one external appliance to transmit stimulation parameters to the at least one stimulator (col. 5, lines 5-8), receiving and storing the stimulation parameters (col. 5, lines 5-28), generating stimulation pulses in accordance with the stimulation parameters (col. 5, lines 1-4), and delivering the stimulation pulses to nerves adjacent to the at least one stimulator (see col. 6, lines 59-63), wherein the stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve (see col. 6, lines 55-57).

Although Schulman et al. do not explicitly discuss a method for treating *chronic* pain, Schulman et al. teach that the device may be used to treat pain in general (see col. 3, lines 30-36). It is further taught that a rechargeable battery may be employed in those applications requiring longer treatment times due to the recurring nature of the ailment (note for example col. 4, lines 40-56 and col. 11, lines 2-16). Given the fact that one of the intended uses of the device is to treat pain via nerve stimulation, and given the teaching that the implant may be powered indefinitely from an external power source depending on the particular application at hand, those of ordinary skill in the art

presented with a patient experiencing chronic pain, would have seen the obviousness of utilizing the method of Schulman et al. to block chronic pain and provide a measure of relief to the patient.

Regarding the step of identifying a patient experiencing sensations of chronic peripheral pain, it is axiomatic that Schulman et al. must identify a patient experiencing pain if they intend to use the device to treat pain as disclosed.

Regarding the limitation concerning peripheral nerves, because the device of Schulman et al. with its relatively small size is capable of being placed in virtually any region of the body that may require nerve stimulation treatment, and because Schulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation. The type of pain to be treated and the physiology of the nervous system would naturally dictate where the most effective application site resides.

Regarding claims 2 and 3 and claims with similar limitations, note the pulse parameters listed in Table I (col. 7).

Regarding claim 4 and claims directed to specific nerves or chronic pain locations, as reasoned above, because the device of Schulman et al. with its relatively small size is capable of being placed in virtually any region of the body that may require nerve stimulation treatment, and because Schulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation.

Regarding claim 9 and claims directed to details of the sensor, note the text abridging cols. 7 and 8.

In regards to claim 10 and similarly worded claims, Schulman shows in Fig. 2 a diagram of the stimulator containing a sensor 188 coupled to the stimulation electrodes.

Regarding claim 15, comments paralleling those made in the rejection of claim 1 apply here as well.

Concerning claim 21, note the text abridging cols. 7 and 8.

Regarding claim 22, Schulman disclose that glucose –a blood borne substance— may be sensed (text abridging cols. 7 and 8).

Response to Arguments

3. Applicant's arguments filed February 16, 2005 have been fully considered but they are not persuasive. While the current amendment to the claims limits the method to the treatment of chronic pain, the examiner does not consider such a limitation to result in a non-obvious difference given the fact that Schulman et al. disclose that their invention is useful in the treatment of pain through nerve stimulation. It is the examiner's opinion that any physician presented with a patient experiencing chronic pain and knowledgeable of the Schulman et al. disclosure, would have seen the obviousness of utilizing the leadless stimulator to treat the patient.

The Terminal Disclaimers submitted October 21, 2004 were approved, thus effectively removing the double patenting rejections.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached M-F at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
April 18, 2005

KENNEDY SCHAETZLE
PRIMARY EXAMINER